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ELI LILLY AND COMPANY

By Paula K Davis

Date May 18, 2004

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	James A. Hoffmann, et al	)	
			)	
Serial No.	:	09/928,198	)	
			)	
International			)	Group Art Unit:
Filing Date	:	August 10, 2001	)	1647
			)	
For	:	FSH Formulations	)	Examiner:
			)	R. Deberry
Docket No.	:	X12383N	)	

**CERTIFICATION UNDER 37 C.F.R. §1.97 (e)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under the guidelines of 37 C.F.R. §1.97(e), I hereby certify that:  
no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this statement.

Respectfully submitted,

Paula K. Davis

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Attorney for Applicants

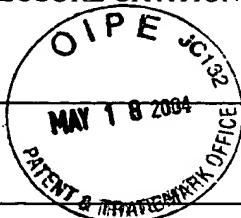
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May 18, 2004

FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X12383N	Serial No 09/928,198
	Applicants James A. Hoffman, et al.	
	Filing Date August 10, 2001	Group 1647



## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
	CCB	AKERS, MICHAEL J. "Excipient – Drug Interactions in Parenteral Formulations." Journal of Pharmaceutical Sciences, Vol. 92, No. 11, November 2002	
	CCC	European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products (CPMP), "Note for Guidance on Maximum Shelf-life for Sterile Products for Human Use After First Opening or Following Reconstitution," Guidance CPMP/QWP/159/96, 1999.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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